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PTO/SB/05 (1/98)

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**UTILITY
PATENT APPLICATION
TRANSMITTAL**
(Only for new nonprovisional applications under 37 CFR 1.53(b))Attorney Docket No. **IAM 498 PA**First Inventor or Application Identifier **Allan Lepine**Title **CANINE MILK SUBSTITUTE**Express Mail Label No. **EE222362510US**JC549
09/163778
09/30/98**APPLICATION ELEMENTS**

See MPEP chapter 600 concerning utility patent application contents.

1. * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original, and a duplicate for fee processing)

2. Specification [Total Pages **15**]

- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. Drawing(s) (35 U.S.C. 113) [Total Sheets **3**]

4. Oath or Declaration [Total Pages **2**]
 a. Newly executed (original or copy)
 b. Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 17 completed)
[Note Box 5 below]
 i. DELETION OF INVENTOR(S)
 Signed statement attached deleting
 inventor(s) named in the prior application, see
 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

5. Incorporation By Reference (useable if Box 4b is checked)
 The entire disclosure of the prior application, from which a
 copy of the oath or declaration is supplied under Box 4b, is
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 application and is hereby incorporated by reference therein.

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6. Microfiche Computer Program (Appendix)

7. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)

- a. Computer Readable Copy
- b. Paper Copy (identical to computer copy)
- c. Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. Assignment Papers (cover sheet & document(s))

9. 37 C.F.R. §3.73(b) Statement
(when there is an assignee) Power of Attorney

10. English Translation Document (if applicable)

11. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations

12. Preliminary Amendment

13. Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)

14. *Small Entity Statement(s) Statement filed in prior application
(PTO/SB/09-12) Status still proper and desired

15. Certified Copy of Priority Document(s)
(if foreign priority is claimed)

16. Other: **Check \$790.00 (filing fee)**

* A new statement is required to be entitled to pay small entity fees, except where one has been filed in a prior application and is being relied upon.

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment:

 Continuation Divisional Continuation-in-part (CIP) of prior application No:

Prior application information: Examiner _____ Group / Art Unit: _____

18. CORRESPONDENCE ADDRESS Customer Number or Bar Code Label : or Correspondence address below
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Complete if Known

Application Number	
Filing Date	September 30, 1998
First Named Inventor	Allan Lepine
Examiner Name	
Group / Art Unit	
Attorney Docket No.	IAM 498 PA

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Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
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106 330	206 165	Design filing fee	
107 540	207 270	Plant filing fee	
108 790	208 395	Reissue filing fee	
114 150	214 75	Provisional filing fee	
SUBTOTAL (1)		(\$) 790.00	

2. EXTRA CLAIM FEES

Total Claims	-20**	=	0	\times	22	=	-0-	Fee from Extra Claims below	Fee Paid
Independent Claims	3	-	3**	=	0	\times	82	=	-0-
Multiple Dependent									

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
103 22	203 11	Claims in excess of 20
102 82	202 41	Independent claims in excess of 3
104 270	204 135	Multiple dependent claim, if not paid
109 82	209 41	** Reissue independent claims over original patent
110 22	210 11	** Reissue claims in excess of 20 and over original patent
SUBTOTAL (2)		(\$) -0-

3. ADDITIONAL FEES

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105 130	205 65	Surcharge - late filing fee or oath	
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	
139 130	139 130	Non-English specification	
147 2,520	147 2,520	For filing a request for reexamination	
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	
115 110	215 55	Extension for reply within first month	
116 400	216 200	Extension for reply within second month	
117 950	217 475	Extension for reply within third month	
118 1,510	218 755	Extension for reply within fourth month	
128 2,060	228 1,030	Extension for reply within fifth month	
119 310	219 155	Notice of Appeal	
120 310	220 155	Filing a brief in support of an appeal	
121 270	221 135	Request for oral hearing	
138 1,510	138 1,510	Petition to institute a public use proceeding	
140 110	240 55	Petition to revive - unavoidable	
141 1,320	241 660	Petition to revive - unintentional	
142 1,320	242 660	Utility issue fee (or reissue)	
143 450	243 225	Design issue fee	
144 670	244 335	Plant issue fee	
122 130	122 130	Petitions to the Commissioner	
123 50	123 50	Petitions related to provisional applications	
126 240	126 240	Submission of Information Disclosure Stmt	
581 40	581 40	Recording each patent assignment per property (times number of properties)	
146 790	246 395	Filing a submission after final rejection (37 CFR 1.129(a))	
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Other fee (specify) _____			
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SUBMITTED BY		Complete (if applicable)	
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CANINE MILK SUBSTITUTE

BACKGROUND OF THE INVENTION

This invention relates to a canine milk substitute, or bitch milk replacer, which substantially supplies the nutritional requirements of nursing puppies.

In recent years, the nutritional requirements of growing puppies as well as adult dogs have been studied; however, little information has been acquired on the composition of canine milk and how it meets the nutritional requirements of nursing puppies. It is generally accepted that milk from the lactating mother provides optimal nutrition to the suckling puppy. Accordingly, milk replacers currently in use have been formulated with the intent of matching the nutrient composition of bitch milk. However, most of the commercially known formulations are based on studies conducted with regard only to crude protein, fat and mineral concentrations in the milk of lactating mothers. See Lonnerdal et al., "Developmental Changes in the Composition of Beagle Dog Milk", *Am. J. Vet. Res.*, Vol. 42:662-666 (1981) and Oftedal, "Lactation in the Dog: Milk Composition and Intake by Puppies", *J. Nutr.*, 114:803-812 (1984). Little study has been devoted to important information such as fatty acid and amino acid profiles in bitch milk and other factors which are believed to have an effect on the nutrient profiles of bitch milk including breed and stage of lactation.

Accordingly, as currently available commercial bitch milk replacers have been formulated based on limited research data, they do not necessarily provide adequate nutrition to the nursing puppy to ensure proper development and growth. Therefore, there is still a need in the art for a canine milk replacer which is based more closely on the actual concentrations of essential nutrients in bitch milk and which substantially supplies the nutritional needs of nursing puppies.

SUMMARY OF THE INVENTION

The present invention meets that need by providing a canine milk substitute, or milk replacer, containing amounts of protein, fat and carbohydrates which closely matches the concentrations of those components in bitch milk. In addition, the milk replacer of the present

invention provides improved fatty acid and amino acid profiles over currently available bitch milk replacers, and has been found to enhance growth in nursing puppies as compared to currently available commercial products.

5 In accordance with one aspect of the present invention, an artificially produced canine milk substitute composition is provided which comprises, on a dry matter basis (DMB), from about 35 to 45% by weight protein, from about 25 to 35% by weight fat, and from about 10 to 25% by weight carbohydrates. In a preferred embodiment of the invention, the composition comprises about 38% protein, about 28% fat, and about 19% carbohydrates.

10 The protein source preferably comprises casein and whey in a weight ratio of about 70:30. The source of fat is preferably selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid and blends thereof.

15 The composition of the present invention also preferably contains fatty acids comprising, as a percentage of total fatty acids on a dry matter basis, from about 15 to 19% palmitic acid, from about 5 to 9% stearic acid, from about 34 to 38% oleic acid, from about 17 to 21% linoleic acid, from about 1 to 4% α -linolenic acid, from about 0.5 to 2% arachidonic acid, from about 0.2 to 1.0% docosahexaenoic acid (DHA), from about 2 to 5% Omega 3 fatty acids, from about 18 to 22% Omega 6 fatty acids, and from about 1 to 4% trans fatty acids. The composition preferably contains 27 to 37% by weight fatty acids on a dry matter basis.

20 The composition also contains essential amino acids comprising, as a percentage of total essential amino acids on a dry matter basis, from about 6 to 10% arginine, 4 to 8% histidine, 8 to 12% isoleucine, 16 to 20% leucine, from about 13 to 17% lysine, from about 2 to 7% methionine, from about 6 to 10% phenylalanine, from about 8 to 12% threonine, from about 1 to 4% tryptophan, from about 9 to 13% valine, from about 2 to 5% cystine, and from about 2 to 6% tyrosine. The composition preferably contains from about 15 to 25% by weight essential amino acids on a dry matter basis.

25 The composition also preferably contains, on a dry matter basis, from about 4 to 8% by weight lactose and from about 0.50% by weight fructooligosaccharide. The composition may also include mixtures of vitamins and minerals.

When the composition of the present invention is fed to puppies in a quantity and frequency appropriate for their nutritional needs, it has been found that the puppies exhibit exceptional growth performance which is superior to other currently available canine milk replacers and which is very similar in pattern to maternally reared puppies.

5 Accordingly, it is a feature of the present invention to provide a canine milk substitute that duplicates canine milk more closely than currently available products and which substantially supplies the nutrient requirements of nursing puppies. Other features and advantages of the invention will be apparent from the following description, the accompanying drawings, and the appended claims.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a bar graph showing percentages of protein, fat and carbohydrates in the composition of the present invention compared with those contained in commercially available bitch milk replacers and bitch milk;

15 Fig. 2 is a bar graph showing the fatty acid profile of the composition of the present invention compared with the profiles of commercially available bitch milk replacers and bitch milk; and

Fig. 3 is a bar graph showing the amino acid profile of the composition of the present invention compared with the profiles of commercially available bitch milk replacers and bitch milk.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The milk substitute composition of the present invention provides an improvement over currently available milk substitutes in that it more closely matches the nutrient profile of bitch milk. The composition of the present invention is higher in protein and lower in fat content than currently commercially available milk replacers. For example, the composition of the present invention preferably comprises at least 38% by weight protein in comparison to currently available milk replacers which comprise only about 29 to 34% protein. In addition, the composition of the

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present invention comprises only about 28% by weight fat in comparison to currently available milk replacers which comprise from about 33 to 42% fat.

The present invention also provides amino acid profiles and fatty acid profiles which are closer to that of bitch milk than commercially available products. When the milk replacer composition of the present invention is fed to puppies on a daily basis, it has been found to provide greater daily weight gain and improved growth performance than commercially available milk replacer products.

The composition is preferably provided in powder form, but may be provided in any suitable form (e.g., liquid) as long as it contains the preferred concentrations of protein, fat, and carbohydrates on a dry matter basis.

A study of bitch milk was undertaken to determine the concentration of true protein, total fat, total carbohydrates, the casein to whey ratio, the amino acid profile, and the fatty acid profile. The testing procedures and results are described below.

Milk samples (approximately 10 mL) were collected from a total of 10 beagle dogs on days 1, 3, 7, 14, 21, 28, 35 and 42 of lactation and stored frozen until subjected to laboratory analysis. All bitches were maintained on the same diet. Bitch and individual puppy body weights were recorded on the days of milk collection.

Nitrogen analysis--Total nitrogen, NPN, and true protein nitrogen were analyzed by micro-Kjeldahl.

Casein:whey ratio--The casein to whey ratio was determined by gel electrophoresis following the determination of the optimal separation conditions for these two class of proteins.

Amino Acids--Amino acid profiles were determined for milk and for the whey and casein proteins.

Fatty Acids--Fatty acids profiles were analyzed by gas chromatography.

Lactose--Lactose was determined by the lactase assay and total lipids via the Folch procedure.

Minerals--Mineral composition was determined by atomic absorption spectrometry.

Milk proteins--Milk protein composition was determined by gel electrophoresis and by FPLC using gel filtration and ion-exchange chromatography. Isolated proteins were identified by N-terminal sequencing.

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Results

Protein concentration was very high in day 1 samples (144 ± 60 g/L), then decreased through day 21 (68 ± 13 g/L); a modest increase was then observed. There was no change in the concentration of NPN (approximately 6-10% of total N). The casein/whey ratio was about 70/30 and stayed constant throughout lactation. Lactose concentration increased during early lactation: day 1 samples contained 17 ± 4 g/L, while day 7 to day 42 samples contained 34-40 g/L. Lipid concentration was high in early lactation(approximately 13%) and then decreased slightly (approximately 11%). Citrate concentration increased from day 1 to day 7 (4.8 ± 1.2 to 6.6 ± 1.0 mM), then gradually decreased by day 42 (3.9 ± 1.2 mM).

Although data was developed through the duration of lactation, only the data for day 7 of lactation are described below. Because milk composition changes throughout the course of lactation and the nutrient needs of puppies are most critical during the first two weeks of life, it was determined that this early milk composition was the most appropriate data upon which to base a single milk replacer formulation. All of the following data are presented on a dry matter basis. The percentages in the essential amino acid and fatty acid profiles are expressed as a percentage of total essential amino acids and total fatty acids, respectively.

Composition

Protein	40.40%
Fat	31.8%*
Carbohydrate	18.5%
Casein/Whey Ratio	70:30

*This value was obtained from Lonnerdal et al., "Developmental Changes in the Composition of Beagle Dog Milk", *Am. J. Vet. Res.*, Vol. 42:662-666 (1981) and Oftedal, "Lactation in the Dog: Milk Composition and Intake by Puppies", *J. Nutr.*, 114:803-812 (1984).

Essential Amino Acid Profile (%)

Arginine	9.70
Histidine	6.37
Isoleucine	8.94
Leucine	22.14
Lysine	8.92
Methionine	5.40
Cystine	3.84
Phenylalanine	7.83
Tyrosine	5.61
Threonine	8.25
Tryptophan	1.06
Valine	11.9

Fatty Acid Profile (%)

Palmitic	24.30
Stearic	2.90
Oleic	36.5
Linoleic	14.5
Arachidonic	1.22
Docosahexaenoic	0.70
Trans Fatty acids	3.40

Based on this data, the bitch milk replacer of the present invention was formulated and

25 preferably contains about 38% protein, about 28% fat, and about 19% carbohydrates. The casein and whey in the composition have a weight ratio of about 70:30.

The source of fat in the milk replacer composition preferably comprises a blend of corn oil, canola oil, butter oil, arachidonic acid, and docosahexaenoic acid. This blend of fats is believed to provide a fatty acid profile which is close to that of bitch milk and comprises from

about 15 to 19% palmitic acid, from about 5 to 9% stearic acid, from about 34 to 38% oleic acid, from about 17 to 21% linoleic acid, from about 1 to 4% α -linolenic acid, from about 0.5 to 2% arachidonic acid, from about 0.2 to 1.0% docosahexaenoic acid (DHA), from about 2 to 5% Omega 3 fatty acids, from about 18 to 22% Omega 6 fatty acids, and from about 1 to 4% trans fatty acids (expressed as a percentage of total fatty acids on a dry matter basis). The fatty acids preferably comprise about 25% to 35%, and most preferably, about 28% of the total composition on a dry matter basis.

The composition also contains amounts of essential amino acids which exhibit a profile similar to that of actual bitch milk. Expressed as a percentage of total essential amino acids on a dry matter basis, the amino acids preferably comprise from about 6 to 10% arginine, 4 to 8% histidine, 8 to 12% isoleucine, 16 to 20% leucine, from about 13 to 17% lysine, from about 2 to 7% methionine, from about 6 to 10% phenylalanine, from about 8 to 12% threonine, from about 1 to 4% tryptophan, from about 9 to 13% valine, from about 2 to 5% cystine, and from about 2 to 6% tyrosine. The essential amino acids preferably comprise about 15% to 25%, and most preferably, about 20% of the total composition on a dry matter basis.

The composition also preferably contains, on a dry matter basis, from about 4-8% by weight lactose and from about 0.50% by weight fructooligosaccharide. Fructooligosaccharide (FOS) is preferably included in the formulation because studies have shown FOS to be beneficial to the intestinal health of many animals. FOS may be metabolized by beneficial intestinal bacterial species, such as *Bifidobacterium*. However, harmful intestinal bacteria, such as *Salmonella*, *E. coli* and *Clostridia* are unable to process FOS. Therefore, FOS appear to promote a healthy intestinal environment in animals.

The composition may also contain vitamins and minerals including, but not limited to Vitamin A acetate, cholecalciferol, d, l-alpha tocopheryl acetate, cyanocobalamin, riboflavin, niacinamide, d-calcium pantothenate, folic acid, thiamin mononitrate, pyridoxine hydrochloride, biotin, inositol, ascorbic acid, dextrose, tricalcium phosphate, potassium chloride, potassium citrate, magnesium sulfate, monosodium phosphate, zinc sulfate, copper sulfate, manganese sulfate, sodium selenite, potassium iodide, cobalt sulfate, and ferric methionine.

In order that the invention may be more readily understood, reference is made to the following example which is intended to illustrate the invention, but not limit the scope thereof.

Example 1

5 A milk substitute was prepared in accordance with the present invention by combining the following ingredients:

Formula A

<u>Ingredient</u>	<u>Percentage</u>
Water	80.0
Na/Ca Caseinate	5.233
Whey Protein Concentrate	3.491
Maltodextrin	2.646
Butter Oil	2.412
Canola Oil	1.764
Mineral Premix ¹	1.147
Lactose	1.134
Corn Oil	.869
Dried Egg Yolk	.506
Emulsifier	.200
Vitamin Premix ²	.128
Arachidonic Acid Supplement	.100
Fructooligosaccharide	.100
L-Histidine HCl	.090
L-Arginine	.060
Choline Chloride	.055
DHA Supplement	.040
Ascorbic Acid	.025

30 ¹The “Mineral Premix” contained one or more of the following: tricalcium phosphate, potassium chloride, potassium citrate, magnesium sulfate, monosodium phosphate, zinc sulfate, copper sulfate, manganese sulfate, sodium selenite, potassium iodide, cobalt sulfate, and ferric methionine.

35 ²The “Vitamin Premix” contained one or more of the following: Vitamin A acetate, cholecalciferol, d,l-alpha tocopheryl acetate, cyanocobalamin, riboflavin, niacinamide, d-calcium pantothenate, folic acid, thiamin mononitrate, pyridoxine hydrochloride, biotin, inositol, and ascorbic acid.

To compare the formulation of the present invention with currently available products, an analysis of several commercially available bitch milk replacer formulas was conducted. The test formulas were JustBorn™ (JBD), available from Farnam Pet Products, Esbilac® Milk Replacer for Puppies (ESB), available from Pet-Ag, Inc., and Nurturall Puppy Balanced Milk Replacer (Nurtal), available from Veterinary Products Laboratory. Table 1 shows the protein, fat and carbohydrate content of those commercial formulas compared with the composition of the present invention (Formula A). Natural bitch milk was used as a baseline value (100)*.

TABLE 1

	Bitch	ESB	JBD	Nurtal	Formula A
Protein	100	83.1	74.4	78.8	96.6
Fat	100	132.6	107	103.6	95
Carbohydrates	100	69.3	114.4	115.3	103.9

As can be seen from Table 1, and as shown in Fig. 1 which is a bar graph of the data shown above, the composition of Formula A is much closer to natural bitch milk than the other products.

The fatty acid and amino acid profiles of the commercially available products were also analyzed and compared with bitch milk and the composition of the present invention as shown below in Tables 2 and 3. The comparisons are expressed as a percent of control (bitch=100%). The values for the amino acids and fatty acids are expressed as a percent of total protein and total lipids, respectively.

*The milk fat values were obtained from Lonnerdal et al., "Developmental Changes in the Composition of Beagle Dog Milk", *Am. J. Vet. Res.*, Vol. 42:662-666 (1981) and Oftedal, "Lactation in the Dog: Milk Composition and Intake by Puppies", *J. Nutr.*, 114:803-812 (1984).

TABLE 2 - FATTY ACID PROFILE

	Control	ESB	JBD	Nurtal	Formula A
5	Palmitic	100	44.4	58.4	53.9
	Stearic	100	517.2	90.3	97.6
	Oleic	100	78.1	73.4	71.8
	Linoleic	100	77.2	309.7	337.9
	Arachidonic	100	6.5	0	0
	DHA	100	8.6	0	0
	Trans Fatty Acids	100	577.9	17.6	62.9

TABLE 3 - AMINO ACID PROFILE

	Bitch	ESB	JBD	Nurtal	Formula A
15	Arginine	100	84.6	71.5	95.4
	Histidine	100	54	55.7	73.3
	Isoleucine	100	106.7	99.8	107.7
	Leucine	100	77.2	68	79.3
	Lysine	100	92.1	146.6	145.9
	Methionine	100	230.3	47	71.7
	Cystine	100	63.8	41.5	53.6
	Phenylalanine	100	105.4	112.3	135.2
	Tryrosine	100	110.6	290.7	132.5
	Threonine	100	120.3	78.8	93.2
	Tryptophan	100	124.6	64.9	163.2
	Valine	100	85.9	78.6	91.1

Figs. 2 and 3 are bar graphs illustrating the data from Tables 2 and 3, which clearly show that the fatty acid and amino acid profiles of the composition of the present invention is much more similar to the bitch milk profile than any of the other products.

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Example 2

To study the effect of diet on serum fatty acid profile and amino acid profile, forty colony bred Beagle puppies from 7 litters were assigned to three treatments: bitch milk (CTL), (n=15) milk replacer I (MR-I) (n=14) comprising 40% protein and 30% fat (an example of the present invention), and milk replacer II (MR-II) (n=11) comprising 33% protein and 40% fat (Esbilac® Milk Replacer for Puppies from Pet-Ag, Inc.). All puppies were allowed to nurse the dam for 24 hours with subsequent milk replacer feedings every 3 hours for days 1-2 and gradually increased to every 6 hours over the duration of the study. MR-I was found to contain higher levels of essential (EAA) and non-essential (NAA) amino acids than MR-II. Puppies fed MR-I were more similar to CTL in serum EAA and EAA:NAA ratio. These data indicate that the serum fatty acid profile and amino acid profile of growing puppies can be influenced by and are reflective of the milk replacer formulation.

Example 3

To determine the effect of milk composition on growth and body composition of puppies, forty colony bred Beagle puppies from 7 litters were randomly assigned to three treatments: bitch milk (CTL) (n=15), milk replacer I (MR-I from Example 2) (n=14), and milk replacer II (MR-II from Example 2) (n=11). All puppies were allowed to nurse the dam for 24 hours. Milk replacer treatments were subsequently fed to the puppies every 3 hours and decreased to 4 feedings/day for the remainder of the study (30 days). No differences were detected in intake between the MR puppies; however, puppies fed MR-I had increased average daily weight gain and gain efficiency over MR-II fed puppies, i.e., when the amount of product consumed was measured against the weight gained, MR-I fed puppies had a greater increase in body weight, indicating that the MR-I formulation is better at meeting the growth needs of puppies. The body composition of puppies fed MR-I did not differ from CTL puppies in body fat

percentage, but was higher in lean tissue than both CTL and MR-II. Puppies fed MR-II were found to have the highest body fat and lowest lean tissue. These data indicate that the MR-I formulation, which was more similar to bitch milk in fatty acid profile and amino acid profile, results in enhanced structural tissue growth indicating an improved nutritional status in neonatal puppies.

While certain representative embodiments and details have been shown for purposes of illustrating the invention, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing from the scope of the invention, which is defined in the appended claims.

What is claimed is:

1. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates.

5 2. The composition of claim 1 in which the source of protein comprises casein and whey in a weight ratio of about 70:30.

3. The composition of claim 1 comprising about 38% protein.

10 4. The composition of claim 1 comprising about 28% fat.

5. The composition of claim 1 comprising about 19% carbohydrates.

15 6. The composition of claim 1 in which the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

20 7. The composition of claim 1 containing fatty acids expressed as a percentage of total fatty acids on a dry matter basis, of from 15 to 19% palmitic acid, from about 5 to 9% stearic acid, from about 34 to 38% oleic acid, from about 17 to 21% linoleic acid, from about 1 to 4% α -linolenic acid, from about 0.5 to 2% arachidonic acid, from about 0.2 to 1% docosahexaenoic acid (DHA), from about 2 to 5% Omega 3 fatty acids, from about 18 to 22% Omega 6 fatty acids, and from about 1 to 4% trans fatty acids.

25 8. The composition of claim 1 containing amino acids expressed as a percentage of total essential amino acids on a dry matter basis of from about 6 to 10% arginine, 4 to 8% histidine, 8 to 12% isoleucine, 16 to 20% leucine, from about 13 to 17% lysine, from about 2 to 7% methionine, from about 6 to 10% phenylalanine, from about 8 to 12% threonine, from about 1 to 4% tryptophan, from about 9 to 13% valine, from about 2 to 5% cystine, and from about 2 to 30 6% tyrosine.

9. The composition of claim 1 containing from about 4 to 8% by weight lactose.
10. The composition of claim 1 containing about 0.50% by weight fructooligosaccharide.
- 5 11. The composition of claim 1 containing from about 27 to 37% by weight fatty acids.
12. The composition of claim 1 containing from about 15 to 25% by weight essential amino acids.
- 10 13. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% by weight carbohydrates, said composition further comprising from about 4 to 8% by weight lactose and about 0.50% by weight fructooligosaccharide.
- 15 14. An artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates, wherein the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

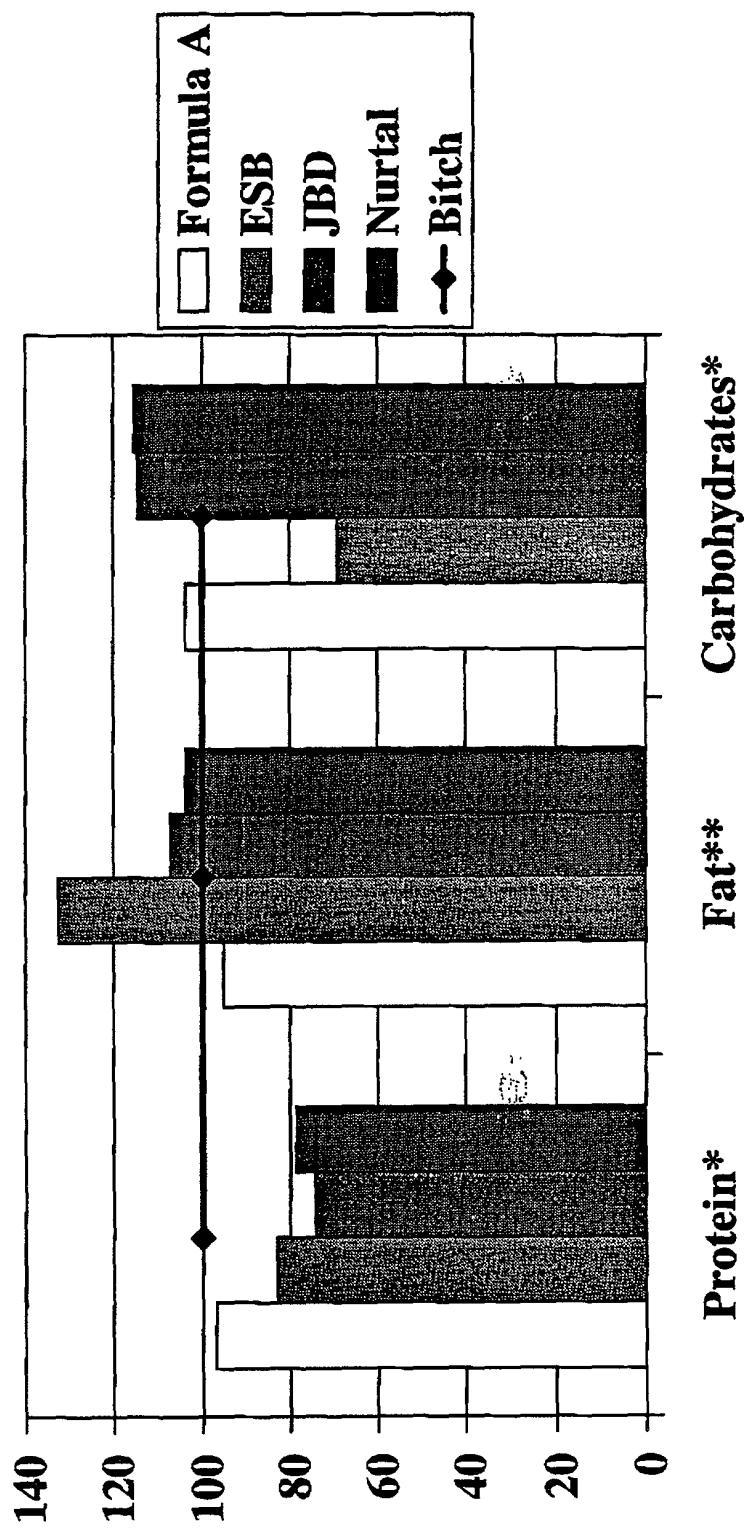
ABSTRACT

An artificially produced canine milk substitute composition is provided which contains, on a dry matter basis, from about 35 to 45% by weight protein, from about 25 to 35% by weight fat, and from about 10 to 25% by weight carbohydrates. The amounts of fat and protein included in the composition provide an essential amino acid profile and fatty acid profile which is close to that of natural bitch milk. The composition may be administered to suckling puppies to provide optimum growth performance.

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Fig. 1.

Compositional Comparisons of Bitch and Commercial Milk Replacers

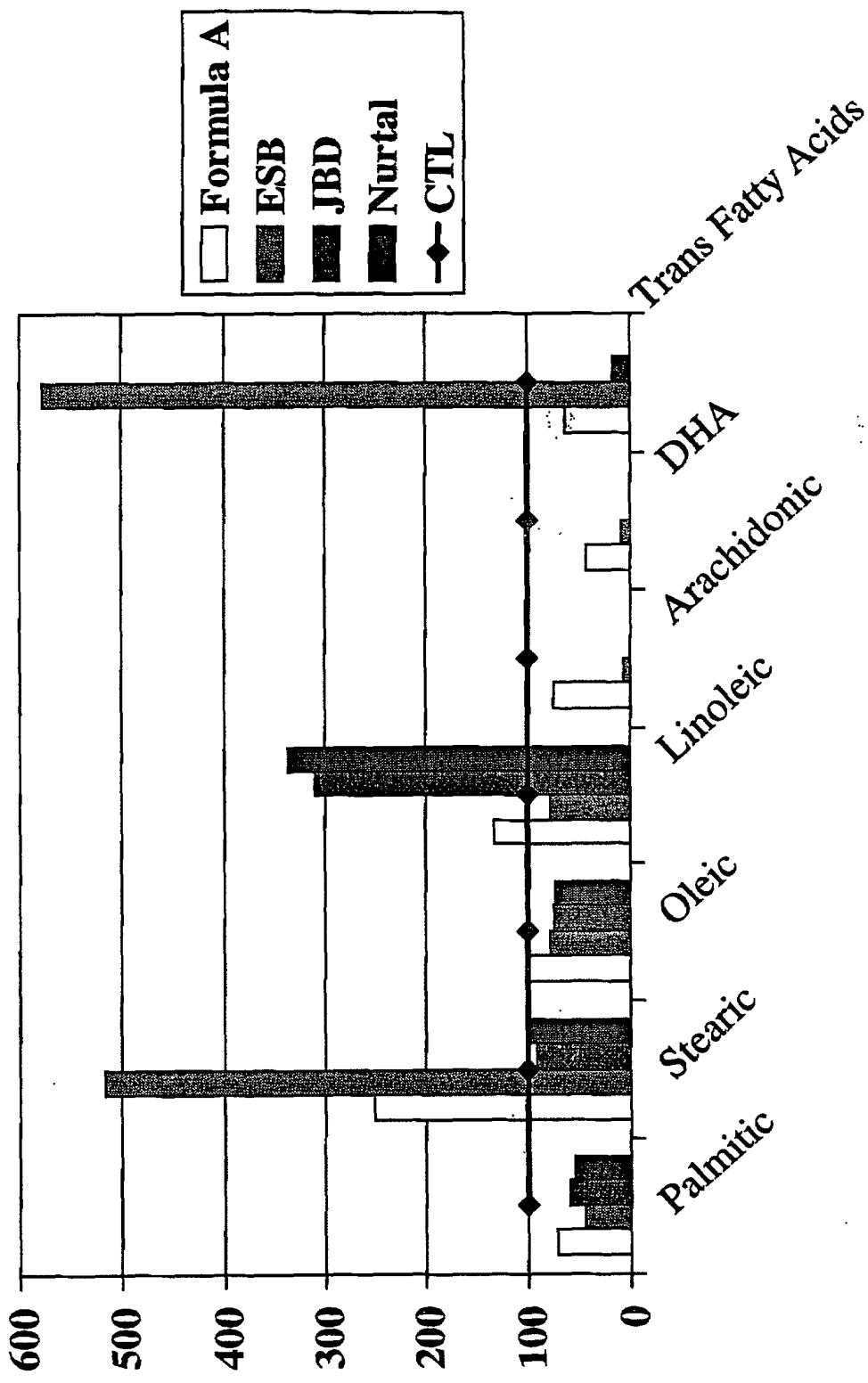


Bitch milk protein and carbohydrate values obtained from Lepine et al., 1998

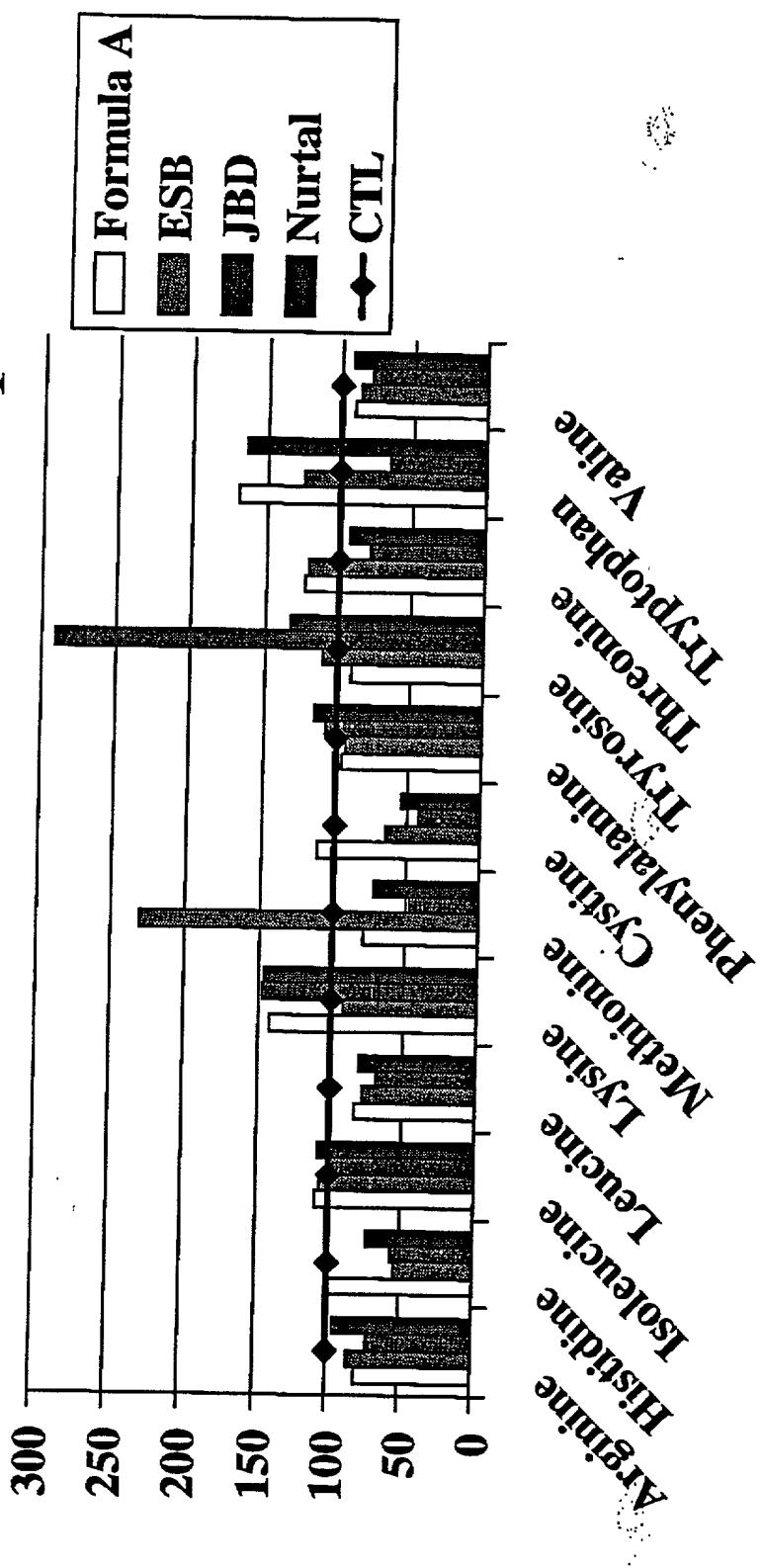
Bitch milk lipid values obtained from Lonnerdal et al. (1980) and Ofstedal (1984).

Fig. 2.

Fatty Acid Compositional Comparisons of Bitch and Commercial Milk Replacers



Amino Acid Compositional Comparisons of Bitch and Commercial Milk Replacers



DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:

CANINE MILK SUBSTITUTE (Our Docket IAM 498 PA), described and claimed

X in the attached specification;
 in the specification filed _____,
as U.S. Application Serial No. _____, and as
amended _____.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims as filed and as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a).

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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